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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/608,918	06/30/2000	Scott R. Presnell	99-50	2697

7590

12/14/2001

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EXAMINER
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PRASAD, SARADA C

ART UNIT	PAPER NUMBER
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1646

7

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/608,918	Applicant(s) PRESNELL ET AL.	
	Examiner Sarada C Prasad	Art Unit 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-7, 17 drawn to a an isolated polypeptide comprising an amino acid sequence of SEQ ID No. 2, classified in class 530, subclass 350.

Group II. Claims 1-7, 17 drawn to a an isolated polypeptide comprising an amino acid sequence of SEQ ID No. 10, classified in class 530, subclass 350.

Group III. Claims 8-13, 20 drawn to an isolated nucleic acid encoding a polypeptide of SEQ ID No. 2, and a method of making the polypeptide and its fusion peptide with an immunoglobulin moiety, and classified in class 435, subclass 69.5.

Group IV. Claims 8-13, 20 drawn to an isolated nucleic acid that encodes polypeptides of SEQ ID No. 10, and a method of making the polypeptide and its fusion peptide with an immunoglobulin moiety, and classified in class 435, subclass 69.5.

Group V. Claims 14, 18, drawn to an antibody to polypeptide regions of SEQ ID NO. 2, classified in class 530, subclass 387.9.

Group VI. Claims 14, 18, drawn to an antibody to polypeptide regions of SEQ ID NO.10, classified in class 530, subclass 387.9

Group VII: Claim 15, 19 drawn to an anti-idiotypic antibody that specifically binds with the antibody to SEQ ID NO. 2, classified in class 530, subclass 387.2.

Group VIII: Claim 15, 19 drawn to an anti-idiotypic antibody that specifically binds with the antibody to SEQ ID NO. 10, classified in class 530, subclass 387.2.

Group IX. Claims 16 drawn to a composition comprising a carrier and the isolated polypeptide of SEQ ID No. 2, classified in class 514, subclass 2.

Group X. Claims 16 drawn to a composition comprising a carrier and the isolated polypeptide of SEQ ID No. 10, classified in class 514, subclass 2.

Group XI Claim 16 drawn to a composition comprising a carrier and an expression vector that comprises a nucleic acid molecule encoding the isolated polypeptide of SEQ ID NO. 2 or a recombinant virus that comprises such an expression vector, classified in class 514, subclass 44.

Group XII Claim 16 drawn to a composition comprising a carrier and an expression vector that comprises a nucleic acid molecule encoding the isolated polypeptide of SEQ ID NO. 10 or a recombinant virus that comprises such an expression vector, classified in class 514, subclass 44.

Inventions I-XII are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which can not be exchanged. For instance, the nucleic acid of inventions III-IV can be used to make hybridization probes or can be used in gene therapy as well as in the production of the protein of interest. The polypeptides of inventions I-II can be used therapeutically or diagnostically, e.g. in screening. Although the antibodies of Groups V-VI can be used to obtain the nucleic acid of Group III-IV, they can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or they may be used therapeutically.

Further, primary antibodies of Groups V-VI and idiotypic antibodies of Groups VII-VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and

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materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case each of these two different types of antibodies can be used independently. In a similar fashion, inventions in Groups III-IV and I-II are also related as a process of making and the product made. In the instant case the polypeptides of SEQ ID NO. 2, and SEQ ID NO. 10 can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols. In fact, these inventions in Groups I-IV are not required for practice of the other.

Inventions IX-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions IX-X are polypeptide compositions, distinct from inventions of XI-XII comprising nucleic acid compositions. They each have distinct methods of preparation and process steps for their use.

Having shown that these inventions are distinct for the reasons given above, they have acquired a separate status in the art shown by their divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

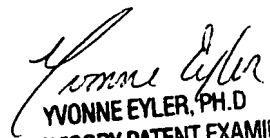
***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday - Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.  
Examiner  
Art Unit 1646  
December 13<sup>th</sup>, 2001

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1000

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